Youth Involvement in the Decision to Start CGM Predicts Subsequent CGM Use

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OBJECTIVE

The ability of continuous glucose monitoring (CGM) to improve diabetes outcomes depends upon consistent use. To identify factors that facilitate long-term use of CGM, this study tested the hypothesis that youth involvement in the decision to initiate this therapy would influence subsequent CGM use and that CGM self-efficacy and satisfaction mediate this relationship.

RESEARCH DESIGN AND METHODS

Before initiating CGM, parent-youth dyads (i.e., pairs) from an academic endocrinology clinic completed assessments, including a measure of the child's involvement in the decision to start CGM. Two months into CGM use, youth completed measures of CGM self-efficacy and satisfaction. Fidelity of CGM use between weeks 5 and 12 was accessed via a cloud-based data repository. Hypotheses were tested with linear mixed-effects models, accounting for patients clustered within provider and repeated measures within patients.

RESULTS

CGM use in 108 dyads (youth mean age 13.4 ± 2.7 years; 73% White) was positively predicted by baseline parent report of youth involvement in the CGM decision ($P < 0.0001$), and this relationship was mediated by youth's perceptions of CGM self-efficacy ($P < 0.0001$) and hassle ($P = 0.014$). So, when the youth shared their opinions about CGM with parents and participated in the decision to start, they perceived higher self-efficacy and lower hassle at 2-month follow-up, which predicted more days of use. This pattern held in models adjusting for youth race and sex and family income.

CONCLUSIONS

To achieve maximum clinical benefit from CGM use, providers should facilitate youth involvement in the decision to initiate the device.

Diabetes technologies, particularly continuous glucose monitoring (CGM), have been advancing rapidly. CGM results in improved glycemic control in studies of youth of all ages (1–5). Near-daily use of the device is required to yield clinical benefit (1,2), but compared with adults, youth are less likely to use CGM consistently (1,6,7). In previous trials, CGM use declined over the 3- to 6-month period after initiation (3,6,8,9), e.g., from 6.8 days per week to 3.7 in youth ages 8–14 years (6) and from 6.3 to 3.3 in adolescents and young adults ages 15–24 years (6). Identifying factors that predict CGM use in youth with diabetes is critical for the development of interventions to increase long-term use of CGM and related emerging technologies (e.g., closed-loop system).

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While consistent CGM use is generally thought to improve health outcomes in youth with type 1 diabetes (2), the decision to start CGM is one for which the preferences and values of the child and family are of paramount importance, especially given the additional burden that CGM creates. A recent consensus statement by an expert panel concluded that the decision to use CGM should be made jointly by the child, parents, and treatment team and that the child should not be a passive bystander to a parental decision (2). However, the extent to which youth involvement is achieved in practice is unknown. Children's decision-making involvement (DMI) in starting CGM may lay the groundwork for effective implementation and management of this technology over time. We define DMI as the way in which children are engaged in decisions, including both degree of child active participation (e.g., child asks for advice, expresses opinion) and degree of adult solicitation of the views and opinions of the child (10). Drawing on social learning theory, we postulate that DMI teaches children the factors to consider when making decisions, the consequences of different options, and the communication skills needed to negotiate and influence decisions. In addition, DMI may enhance self-efficacy (11–13), increase satisfaction with care, and promote adherence (14–17).

The primary goal of this prospective study was to test the hypothesis that the degree of children's involvement in the decision to add CGM to their treatment regimen would impact CGM use 2 months after starting the device and that CGM self-efficacy and CGM satisfaction would mediate this relationship. This hypothesis is based on the assumption that when youth are more involved in the decision-making process, they will have more appropriate expectations of the device and increased self-efficacy related to the device, which, in turn, will enable them to better tolerate device-related problems and overcome barriers to CGM use (9,18–20).

RESEARCH DESIGN AND METHODS

Recruitment

The majority of participants were recruited from the Diabetes Center for Children at Children's Hospital of Philadelphia between June 2017 and April 2019. Several participants ($n = 3$) were recruited from pediatric endocrinology at University of Florida (UF) Health Shands Children's Hospital. Participants were children and one parent/caregiver (hereafter referred to as "parent"). The children were between the ages of 8 and 17 years with type 1 diabetes for at least 6 months for whom CGM was being added to their treatment regimen. We focused on a single CGM brand (Dexcom, either G4/G5 or G6) to reduce variability in outcomes due to device type. The parent and child were English-speaking, willing to start using the device within 3 days after CGM initiation training, and using either an insulin pump or basal-bolus injections. Use of CGM with real-time glucose feedback in the 6 months preceding enrollment, the presence of developmental delay, or psychiatric hospitalization of the child in the past year was exclusionary.

Potential participants were identified via weekly reports of patients for whom a letter of medical necessity for CGM (required by insurance companies in the United States for coverage of CGM-related costs) had been uploaded into the electronic medical record and by review of outpatient clinic schedules. Of the 163 potential participants who were able to be contacted by telephone and deemed eligible, 130 (79.8%) consented and were enrolled in the study. Of these, 22 were withdrawn by study personnel because they no longer met eligibility criteria (e.g., no longer getting CGM or new psychiatric hospitalization), did not start CGM within our study timeline, or were lost to follow-up. Thus, our final sample consisted of 108 participant dyads (i.e., pairs).

Procedures

The study was approved by the institutional review board. Eligible families were called to provide consent/permission and assent. Each dyad was scheduled to be assessed two times over an 8-month period. The research team attempted to collect baseline questionnaires within 1 month of the medical necessity letter for CGM (but prior to the child starting CGM) and follow-up questionnaires 2 months after the CGM start date. The research team accessed CGM data 1 month after the follow-up assessments.

Primary Measures

Decision-Making Involvement

Youth and parents completed the Decision-Making Involvement Scale (DMIS) (10,21) at baseline. The interviewer instructed youth and parents to think about discussions with one another about the CGM decision and respond to items about what each said or did during the discussion. The response options were "not at all," "a little bit," "quite a bit," and "a lot." The DMIS yields five subscales: Parent Seek (e.g., ask for child's opinion, solicit questions), Parent Express (e.g., give information, express opinion), Child Seek (e.g., ask for information, advice), Child Express (e.g., express opinion, give information), and Joint (e.g., negotiate). Responses to this scale were generally reliable with internal consistencies (α) ranging from 0.58 to 0.71 for youth report and from 0.65 to 0.71 for parent report. Two subscales with internal consistency below 0.60, child report of Child Express and child report of Joint, were omitted from further analysis.

CGM Satisfaction

Youth completed the CGM Satisfaction Scale (19) at follow-up, which assesses perceived benefits and hassles of CGM use. Cronbach's α was 0.88 for benefit and 0.92 for hassle.

CGM Self-Efficacy

Youth completed the CGM Self-Efficacy surveys (20) at follow-up to measure their confidence in managing both the technological and behavioral components of using CGM. Cronbach's α was 0.83 in the version for 8- to 12-year-old patients and 0.84 in the version for $\geq$13-year-old patients.

CGM Use

Research staff accessed the Dexcom CLARITY clinic portal (a cloud-based data repository) to document each participant's weekly days of use during weeks 5 through 12 after CGM initiation. The CLARITY portal counts a day of use as one for which at least 50% of CGM readings are available, which equates to at least 144 readings in a 24-h period.

Medical Chart Review

The electronic medical record for each participant was reviewed at both baseline and follow-up to document most recent HbA_{1c}.

Analyses

Standard descriptive statistics were used to summarize baseline patient characteristics. On the basis of skewness values $<$2.00, none of the variables required transformation. Linear or generalized linear

mixed-effects models were used to compare the continuous and categorical variables, respectively, by demographic characteristics, accounting for patients clustered within providers. Hierarchical linear mixed-effects models were used to assess whether days of CGM use per week changed over time, accounting for within-patient correlation due to repeated measures as well as clustering of patients within providers. The within-patient correlation was modeled using a first-order autoregressive (AR1) covariance structure, which assumes that the correlation between two adjacent measures declines exponentially as the time between the two measures increases, and the within-provider clustering was modeled using an interchangeable correlation structure. Polynomial terms of time were considered in the models to capture the potential nonlinear trend of days of use over time. We performed univariate linear mixed-effects models to assess whether each of the variables (demographics, DMIS subscales, CGM self-efficacy, CGM benefit, and CGM hassle) predicted days of use, with time included in the model. Prespecified interaction terms were tested in the models. We calculated effect size as partial η^2, which indicates the proportion of variance in the dependent variable that is attributable to the independent variable (small = 0.01; medium = 0.06; large = 0.13).

We applied the widely used causal steps approach to assess predetermined mediation paths outlined in the classic work of Baron and Kenny (22) and Kenny et al. (23), which involved three regression models to establish mediation: *1*) effect of the predictor (i.e., DMIS subscale score) on the outcome (i.e., days of use); *2*) effect of the predictor on the mediator (i.e., CGM self-efficacy, CGM benefit, and CGM hassle); and *3*) effect of the predictor on the outcome when the mediator was also included in the model. The Sobel test was then used to test whether the reduction in the effect of the independent variable, after including the mediator in the model, was significant (24). For the mediation analyses, we considered child age, sex, and race and family income and structure (two parents, two-parent step-family, and single parent) as potential covariates. On the basis of P values <0.10 of these potential covariates in each mediational path, we retained child sex and race and family income in adjusted mediation models.

RESULTS

Sample

Demographic, diabetes, and CGM characteristics are presented in Table 1. Of the 108 dyads in the sample, 106 (98%) completed their baseline surveys; 1 dyad (1%) did not complete the baseline survey; and, for 1 dyad (1%), only the parent completed the baseline survey. A total of 97 dyads (90%) completed the follow-up survey; 10 dyads (9.3%) did not complete the follow-up survey; and, for 1 dyad (1%), only the parent completed the follow-up survey. Results of χ^2 and t tests indicated that there were no differences between participants with ($n = 98$, based on parent follow-up) and without ($n = 14$) follow-up survey data with respect to demographics (child age, sex, race, ethnicity, and duration of diagnosis; family income; and family structure), baseline questionnaire scores, baseline HbA_{1c}, or CGM days of use for weeks 5–12 (all $P > 0.05$).

We had complete CGM data (i.e., data for weeks 5–12) for 95 (88%) participants and partially complete CGM data for 4 (3.8%) participants. CGM data were unavailable for 9 (8.3%) participants. There were no differences between participants with ($n = 99$) and without ($n = 9$) CGM days of use data with respect to demographics (child age, sex, race, ethnicity, and duration of diagnosis; family income; and family structure), baseline questionnaire scores (DMIS subscale scores), baseline and follow-up HbA_{1c}, and follow-up questionnaire scores (parent and child CGM self-efficacy, parent and child CGM benefit and hassle) (all $P > 0.05$).

Days of Use

Mean ± SD days of use were 5.34 ± 2.75 (range 0–7; median = 7, interquartile range = 5–7) at week 5 and 4.32 ± 3.04 (range 0–7; median = 6, interquartile range = 0–7) at week 12. Overall, statistical modeling indicated that CGM days of use declined by 0.15 days each week during weeks 5 through 12 (B = −0.15 [0.03], 95% CI = −0.22, −0.08, $P < 0.0001$, $\eta^2 = 0.02$), reflecting an overall predicted decline of 1.2 days from weeks 5 to 12. There were trends for youth on insulin pumps (versus basal bolus injections; B = 0.71 [0.37], 95% CI = −0.03, 1.44, $P = 0.06$) and using a smart phone (versus receiver; B = 0.94 [0.55], 95% CI = −0.14, 2.01, $P = 0.09$) to have more days of use. Device type (G4/G5 versus G6) did not predict days of use ($P > 0.25$).

DMI, Self-Efficacy, and Satisfaction as Predictors of CGM Use

Parent report of Child Express positively predicted days of use, such that for each one-point increase in the Child Express subscale score, there was a 0.96 increase in days of use (B = 0.96 [0.24], 95% CI = 0.50, 1.42, $P < 0.0001$, $\eta^2 = 0.02$). In addition, parent report of Parent Express negatively predicted days of use, such that for each one-point increase in the Parent Express subscale score, there was a 0.87 decrease in days of use (B = −0.87 [0.32], 95% CI = −1.49, −0.25, $P = 0.0064$, $\eta^2 = 0.01$). In other words, when parents reported that children spoke up more in discussions about CGM, by sharing information and opinions about CGM, children had higher days of use at follow-up. Conversely, when parents reported that they themselves spoke up more in discussions about CGM, by sharing information and opinions about CGM, children had lower days of use at follow-up. The other DMIS subscales (child and parent report of Child Seek, child and parent report of Parent Seek, child report of Parent Express, and parent report of Joint did not predict days of use. As expected, higher CGM self-efficacy (B = 0.10 [0.02], 95% CI = 0.06, 0.14, $P < 0.0001$, $\eta^2 = 0.03$) and CGM benefit (B = 2.10 [0.42], 95% CI = 1.29, 2.92, $P < 0.0001$, $\eta^2 = 0.03$) and lower CGM hassle (B = −1.01 [0.33], 95% CI = 1.66, −0.35, $P = 0.0026$, $\eta^2 = 0.01$) predicted more days of use.

Mediation Analyses

To examine mediation in the prediction of days of use by parent report of Child Express and Parent Express, we first tested whether parent report of Child Express and Parent Express predicted CGM self-efficacy, CGM hassle, and CGM benefit. Parent report of Child Express predicted both CGM hassle (B = −0.18 [0.03], 95% CI = −0.23, −0.13, $P < 0.0001$, $\eta^2 = 0.06$) and self-efficacy (B = 3.14 [0.46], 95% CI = 2.25, 4.04, $P < 0.0001$, $\eta^2 = 0.05$). In other words, when parents reported that children spoke up more in discussions about CGM, by sharing information and opinions about CGM, children had higher CGM self-efficacy and perceived lower CGM hassle at 2-month follow-up. Parent report of Child

Table 1—Demographic, diabetes, and CGM characteristics

Variable	Value
Institution	
CHOP	105 (97.2)
UF Health Shands Children's Hospital	3 (2.8)
Child age (years)	13.35 ± 2.74, 8–17
Child sex (female)	49 (45.8)
Child race	
White	78 (72.9)
African American	17 (15.9)
Asian	4 (3.7)
Other	8 (7.5)
Child Hispanic ethnicity (yes)	14 (13.1)
Parent sex (female)	101 (94.4)
Income	
<$20,000–$39,999	14 (13.1)
$40,000–$59,999	10 (9.4)
$60,000–$79,999	14 (13.1)
$80,000–$99,999	12 (11.2)
≥$100,000	54 (50.5)
Refused	3 (2.8)
Parent education	
Some or completed high school	17 (15.9)
Some college or technical school after high school	16 (15)
College graduate	49 (45.8)
Some postcollege graduate education	3 (2.8)
Master's, PhD, MD, law degree, and others	22 (20.6)
Employment status	
Not currently employed	21 (19.6)
Working part-time	17 (16)
Working full-time	69 (64.5)
Family structure	
Two parents	74 (69.2)
Two parents (step-family)	12 (11.2)
Single parent	21 (19.6)
Insulin delivery	
Pump	54 (50)
Basal bolus injections	54 (50)
Illness duration (years)*	5.33 ± 4, 0.28–16.12
HbA_{1c} (CHOP only)	
Baseline (%)	8.18 ± 1.70, 5.2–14
Baseline (mmol/mol)	66 ± 18.6, 33–130
Follow-up (%)	7.97 ± 1.54, 5.2–14
Follow-up (mmol/mol)	64 ± 16.8, 33–130
Dexcom device type	
G4/G5 with receiver	7 (7.1)
G5 with smart phone	40 (40.4)
G6 with receiver	6 (6.1)
G6 with smart phone	46 (46.5)

Data are *n* (%) or mean ± SD, range. *There were two child participants whose parents indicated that the duration of diagnosis was >6 months during screening, but medical chart review at a later date indicated duration of diagnosis <6 months (one was 5.5 months; one was 3.4 months). We opted to retain these participants in the analysis. CHOP, Children's Hospital of Philadelphia.

Express did not predict perceived CGM benefit, and parent report of Parent Express did not predict CGM self-efficacy, hassle, or benefit (all $P > 0.05$).

On the basis of the pattern of findings, there were two potential mediational paths to test. One path had CGM self-efficacy as a mediator of the relationship between parent report of Child Express and days of use, and the other path was analogous but had CGM hassle as the mediator. Figure 1 depicts the results of the mediation analyses. After accounting for the effect of CGM self-efficacy on days of use, the association between Child Express and days of use decreased and was no longer statistically significant (B = 0.50, SE = 0.27, 95% CI = −0.03, 1.04, $P = 0.065$, $\eta^2 = 0.00$). The Sobel test confirmed statistically significant mediation ($Z = 3.72$, $P < 0.0001$). CGM self-efficacy accounted for ∼28% of the effect of Child Express on days of use. After accounting for the effect of CGM hassle on days of use, the association between Child Express and days of use decreased but was still statistically significant (B = 0.65, SE = 0.27, 95% CI = 0.12, 1.19, $P = 0.017$, $\eta^2 = 0.01$). The Sobel test confirmed statistically significant partial mediation ($Z = 2.50$, $P = 0.014$). CGM hassle accounted for ∼17% of the effect of Child Express on days of use. The pattern of findings related to mediation was similar in models adjusting for child sex and race and family income (data not shown).

CONCLUSIONS

To achieve the clinical benefits of CGM, near-daily or daily use is necessary (1,2), and prior research suggests that children and adolescents use CGM less consistently than adults (1,6,7). The current study examined decision making about CGM prior to starting the device, assessed CGM self-efficacy and satisfaction 2 months after starting the device, and used an objective measure of adherence (days of use accessed from Dexcom CLARITY portal) for weeks 5 through 12 after device initiation. As expected, days of use declined significantly from weeks 5 to 12. Youth involvement in the decision to start CGM predicted more days of use, in part via greater CGM self-efficacy and lower perceived hassle.

Only parent-reported DMI, and not child-reported DMI, predicted days of use. One possible reason is that parents were more attuned to the nuances in parent-child communication about the CGM decision. Alternatively, it could be that parents who reported higher levels of child involvement in discussions about the device were also those who provided more oversight and control of device use following initiation. It is also possible that child perceptions were important, but one of the child-reported subscales, child report of Child Express, was not used in the analysis because of low internal consistency; this was not expected based on prior research using the measure in samples of youth with type 1 diabetes

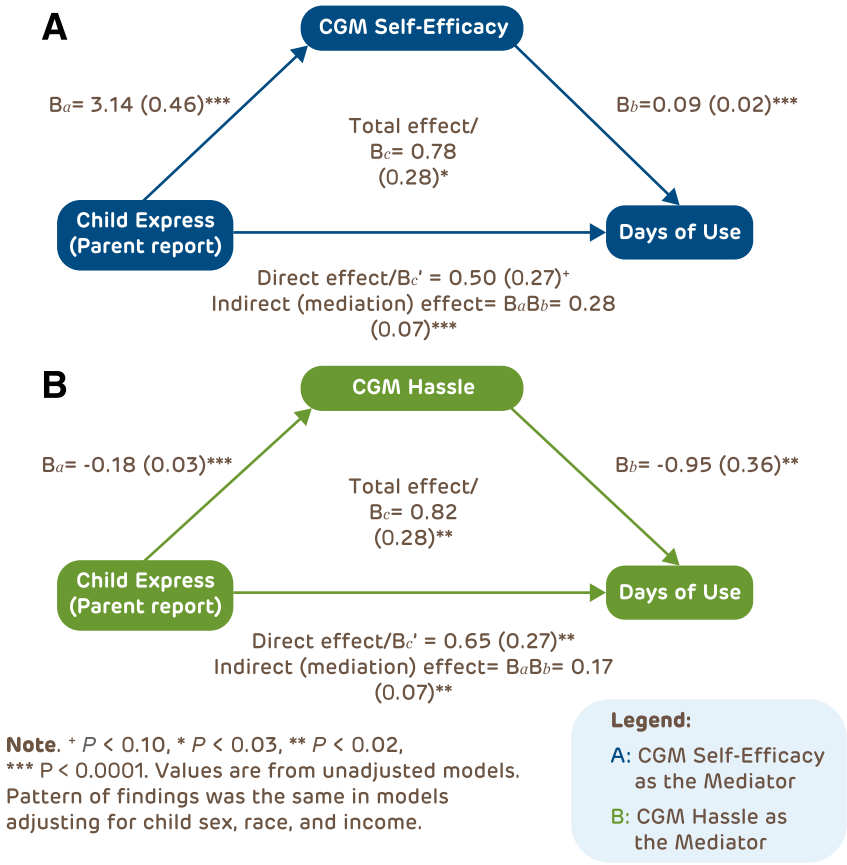

Figure 1—Mediation analysis. *A*: CGM self-efficacy as the mediator. *B*: CGM hassle as the mediator.

(10,21). Parent report of Child Express predicted youth perceptions of both CGM self-efficacy and hassle, such that children who were more involved in discussions about CGM, by sharing information and opinions, reported higher CGM self-efficacy and lower CGM hassle at 2-month follow-up. Self-efficacy has been identified as an important predictor of adherence in youth with type 1 diabetes, including adherence to CGM use, as found in the current study and prior research (20). Facilitating youth's active involvement in decisions about the treatment regimen sends the message that his or her role is important and may foster a sense of competence with respect to type 1 diabetes management, including use of advanced technologies. However, this relationship is likely to be bidirectional, with youth who are more confident being more likely to speak up in treatment-related discussions with their parents and providers.

Interestingly, when parents reported that they spoke up more in discussions about the CGM decision, by sharing information and opinions about CGM with their children, children had lower days of use at follow-up. However, this relationship was not mediated by youth CGM self-efficacy or satisfaction. Although the concept of DMI underscores that provision of information and guidance to children is important, this subscale may have captured parental dominance or persuasion during discussions about getting the device with youth who were already resistant to the device and, therefore, less likely to use it consistently.

The present findings should be interpreted in light of several limitations. The sample was primarily non-Hispanic White, parent participants were mostly mothers, and CGM device type was limited to one brand. As such, the findings may not be generalizable to more diverse samples, father-youth dyads, or youth/families using different CGM brands. Furthermore, the results may not be generalizable to youth or families who are more overwhelmed with diabetes management or less open to talking about diabetes, as they appeared to be less likely to participate in the study. The follow-up period was relatively short, so we cannot say whether the effects of DMI persist over time. This is especially important because prior research has demonstrated that CGM sensor use in children continues to decrease after 3 months (20,25), and multiple other factors, not measured in the current study, are likely to contribute to this downward trajectory in the long term. Finally, anecdotal clinical evidence suggests that increasing numbers of youth are starting CGM immediately after diagnosis and at younger ages, when parents are more likely the primary driver of treatment decisions. As CGM becomes more routine (26), especially given the potential benefit of early CGM initiation (27) (i.e., within 12 months of diagnosis), the decision-making process about initiating CGM may be less salient for both families and providers. However, even when CGM is initiated at a young age, it would be valuable to continue to assess youth's preferences regarding CGM as they mature and gain experience with the device.

Future research is needed with longer follow-up periods to examine whether the impact of DMI on self-efficacy, satisfaction, and days of use persists with time. It is possible that youth who have an unsuccessful introduction to CGM may be resistant to try it again in the future and/or have negative expectations of device use. Additional research is needed to develop intervention strategies to enhance children's involvement in the decision about CGM, prevent declines in CGM use over time, and maximize the clinical benefits that can be obtained by appropriate use of CGM and other emerging technologies for diabetes management. Such research should also target more diverse samples to examine the extent to which sociodemographic factors, such as race, ethnicity, and socioeconomic status, impact CGM uptake and use. Enhancing CGM use in populations at risk for poor glycemic control could be one effective way to reduce disparities that are evident in both youth and adults with type 1 diabetes (28). Finally, future research should take a broader view of the decision-making process by assessing a multidimensional array of other factors that may influence initiation and use of medical devices, such as health literacy, comfort with technology (e.g., early versus late adopters), and clinician bias in recommending medical devices.

To maximize the clinical benefits of CGM, our results suggest that providers should facilitate youth involvement in decision making, by eliciting their opinions, concerns, and questions about the device and providing information about the device directly to the child/adolescent. Assessing children's and adolescents' expectations of device use and addressing misconceptions are also important, as perceived hassle and benefit both predicted days of use in our sample. Providers can also encourage parents to engage their children in discussions about the decision and avoid dominating discussions about CGM, which may increase the likelihood that they are in agreement about waiting or proceeding with device initiation. If a child or adolescent does not have a role in the decision and/or is not ready and willing to start CGM, they are less likely to be satisfied with the device and use the device consistently. Interest in CGM should be revisited over time because the child's preferences are likely to evolve with changes in development and experience.

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Author Contributions. V.A.M. conceptualized and designed the study, designed the data collection instruments, supervised data collection, drafted the initial manuscript, and reviewed and revised the manuscript. R.X. supervised the statistical analyses and reviewed and revised the manuscript. N.S. collected data, drafted the methods section of the manuscript, and reviewed and revised the manuscript. C.F. and S.M.W. conceptualized and designed the study and reviewed and revised the manuscript. V.A.M. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Prior Presentation. This study was accepted as a poster at the Pediatric Academic Societies Annual Meeting, May 2020, Philadelphia, PA. Although the meeting was canceled due to coronavirus disease 2019, the poster abstract is included in the online meeting materials.

Appendix

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